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BANNER & WITCOFF, LTD.
28 STATE STREET
28th FLOOR
BOSTON, MA 02109-9601

EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,428	VERLAAN ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-55,61-87 and 89* is/are pending in the application.

4a) Of the above claim(s) *77-84,87 and 89* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-55, 61-76 and 85-86* is/are rejected.

7)☐ Claim(s) _ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants Response to Restriction Requirement Acknowledged

1. Applicant's election, with traverse, with the Group I, claims 46-55, 61-76 and 85-86, is acknowledged.

Applicant traverses the restriction requirement based on grounds that there would be no burden in searching the subject matter of the claims 46-55, 61-87 and 89 which filed on 02/21/06.

This argument is not persuasive, as claimed invention would be distinctive, each from the other for the reason of the record. Furthermore, the search of the entire groups in the non-patent literature (a significant part of a thorough examination) would be burdensome. Therefore, the requirement between (i) a fluid, (ii) a process of using said fluid and (iii) a process of making said fluid is still deemed proper, and made Final.

However, the examiner will not maintain the election of species requirement among the groups in light of the amendment.

Accordingly, claims 77-84, 87 and 89 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 46-55, 61-76 and 85-86 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fluid for treating hypohydration, does not reasonably provide enablement for a fluid for "preventing". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The claims are directed to a fluid composition for "preventing" hypohydration, comprising at least one of methyl amine selected from dimethylglycine and sarcosine in the amount of 0.2-10g/l, one or more digestible carbohydrates in the amounts of 20-75 g/l, and one or more minerals selected from calcium and magnesium, wherein said fluid has an essentially hypotonic osmolarity in the range of 70 to 275 mgOsm/l.

. It is recited that the instant compounds are useful in the "prevention" of hypohydration for which applicants provide no competent evidence. "To prevent" actually means to anticipate or counter in advance, to keep from happening etc. (as per Websters 11 Dictionary) and therefore it is not understood how one skilled in the art can reasonably establish the basis and the type of

subject to which the instant compounds can be administered in order to have the "prevention" effect. The only example in the specification provides how to make said fluid composition, however, it is inconceivable as to how the claimed compositions, not only treat but also "prevent" the condition claimed by the instant invention. Further, there is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the diseases or disorders claimed herein.

The relative skill of those in the art of pharmaceuticals and unpredictability of the pharmaceutical art is high. As discussed above, the specification does not provide any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Since the efficacy of said composition in preventing "hypohydration" cannot be predicted from a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to use the invention commensurate in scope with the claims.

3. Claims 48, 63, 64, 65, 66 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48, 63, 64, 65, 66 and 75 recite "a dry mass content of 9 wt. % or less", "the magnesium concentration is 100 mg/l or more", "the zinc concentration is 10 mg/l or more", "the calcium concentration is 300 mg/l or more", "the iron concentration is 5 mg/l or more" and "nitrogen content of less than 3 g/l" respectively.

With respect to claims 48 and 75, it is not clear what is lower limit of the claimed dry mass content or nitrogen content in said composition. Since the interpretation of the claimed range allows for the inclusion of zero, the claims leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

With respect to claims 63-66, it is not clear what is upper limit of the claimed mineral concentration. The specification does not define the upper limit of the claimed range of magnesium, zinc, calcium and iron concentration, therefore, the claim renders for the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 46-55, 62-71, 73-76, 85 and 86 are rejected under 35 USC 103(a) as being unpatentable over Simone (US 5397786) in view of Thomas et al. (US 5972985), Buchholz et al. (US 6514973) and Hageman et al. (US 6420342 B1).

The claims read on fluid composition comprising at least one of methyl amine selected from dimethylglycine and sarcosine in the amount of 0.2-10g/l, one or more digestible carbohydrates in the amounts of 20-75 g/l, and one or more minerals selected from calcium and magnesium, wherein said fluid has an essentially hypotonic osmolarity in the range of 70 to 275 mgOsm/l.

Simone teaches a hypotonic rehydration or nutritional drink, comprises 1 to 30mg of betaine and methionine, choline, 1 to 100g of carbohydrates in the form of monosaccharides, oligosaccharides and/or polysaccharides (e.g., glucose, glucose polymers, ribose, mannose, fructose, galactose, maltodextrin, maltose, etc...), 2 to 2500mg of minerals (e.g., magnesium, calcium, sodium, potassium, etc...), vitamins (e.g., vitamin C, vitamin E, etc...), wherein said composition is useful for treating dehydration symptoms due to exposure to high temperature and/or heavy physical exercise, severe diarrhea or vomiting for a variety of causes such as gastrointerstinal disorders, cardiovascular disorders, and chronic illnesses such as cancer

(column 2, line 45 thru column 4, line 22; Table 1; column 5, lines 37-55; Claims 13-14 and 17-18).

Thomas teaches a rehydration or nutritional solution comprising histidine, vitamins (i.e., vitamin C, ascorbate, vitamin E, beta-carotene, vitamin A), glycerol, minerals (i.e., copper, iron, magnesium, manganese, zinc, iron, selenium) and lipoic acid (abstract; column 7, line 25; column 9, line 60 thru column 11, line 22; column 11, lines 33-35).

Buchholz teaches sarcosine or dimethylglycine as functional equivalent to betaine as a methyl donor (column 3,lines 6-8; column 4, lines 62-65).

Hageman teaches a nutritional composition containing carbohydrates (e.g., ribose, maltodextrin), taurine, alpha-lipoic acid, folic acid, citrate or phosphate in the form of electrolytes (e.g., magnesium phosphate and zinc citrate), vitamins (e.g., B1, B6 and B12), betaine, choline, protein and histidine that is useful for trauma, surgery, cancer, rehydration, cardiovascular or cerebrovascular disorder (Table 1; column 13, lines 22-35; claims).

The teaching of Simone differs from the claimed invention in (i) the use of other methyl amine such as dimethylglycine and sarcosine in said composition; (ii) the specific osmolarity of said composition, "in the range of 70 to 275 mOsm/l" (claim 46); (iii) the specific dry mass content of ingredients in said composition, "a dry mass content of 9 wt% or less" (claim 48); (iv) the specific amounts of active and inactive ingredients in a composition, "the amount of methyl amine being between 01.2-10 g/l" and "the digestible carbohydrate is in the amount of between 20-75 g/l" (claim 46), "the digestible carbohydrate concentration is between 10 and 80 g/l" (claim 49), "at least 0.5 g/l of the digestible carbohydrate is ribose or innositol" (claim 50), "fructose and mannose together are present in an amount between 0.05-06 mole per mole

glucose" (claim 54), "one or more carbohydrates comprises at least 0.5 g/l ribose, at least 0.5 g/l inositol and/or at least 0.5 g/l galactose" (claim 55), "the mineral concentration is between 0.1 and 30 g/l" (claim 61), "the magnesium concentration if 100mg/l or more" (claim 63), "the zinc concentration is 10mg/l or more" (claim 64), "the calcium concentration is 300 mg/l or more" (claim 65), "the iron concentration is 5mg/l or more" (claim 66), "glycerol is present in a concentration of 0.1-20 g/l" (claim 67), "lipoic acid is present in a concentration of at least 20 mg/l" (claim 68), "taurine is present in a concnetraiton of 0.1-2 g/l and wherein citrate is present in a concentration of 0.2-2 g/l" (claim 71), "caffeine is present in a concentration of 0.1-1 g/l" (claim 72) and "a nitrogen content of less than 3 g/l" (claim 75); (v) the specific mixtures of carbohydrates in a composition; (vi) the specific pH of the claimed invention, "in the range of 2.5-6.8" (claim 74); and (vii) the incorporation of secondary ingredients such as zinc, iron, glycerol, lipoic acid, taurine and citrate in said composition.

However, it would have been obvious to a person skill in the art, at the time of the invention was made, to arrive at the claimed invention containing all the ingredients herein (a methyl amine (source of nitrogen), vitamins, carbohydrates, glycerol, minerals, lipoic acid, etc...). All the ingredients employed herein are known to be useful in preparing rehydration drink or solution. Furthermore, one having ordinary skill in the art would have expected that substitution of betaine with other known methyl donor such as dimethylglycine and sarcosine would provide similar activity of the compound of the reference due to their art-recognized equivalent functional property. Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference.

Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

In addition, it would have been apparent to those skilled in the art to optimize amounts of known active and inactive ingredients in a composition; the specific pH of the final composition; the dry mass of the ingredients in a composition; the specific mixtures of kwon digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose, inositol); and concurrent administration regimens as determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate dosage amounts for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed herein.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

5. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simone (US 5397786) in view of Thomas et al. (US 5972985), Buchholz et al. (US 6514973) and Kampinga

et al. (US 6455511 B1) and further in view of Kuznicki et al. (US 5464619). See above 35 USC 103(a) rejection.

The modified teaching of Simone includes all that is recited in claims 25 and 28 except the incorporation of caffeine into said composition.

Kuznicki teaches a rehydration composition containing electrolytes, carbohydrates or carbohydrate derivatives (e.g., fructose, glucose, maltodextrin, glycerol), caffeine and vitamins (abstract, column 4, lines 53-61; column 6, lines 37-44).

To incorporate such teaching into the teaching of Simone, would have been obvious in view of Kuznicki who teaches the use of caffeine in rehydation solution.

Above references in combination makes clear that the use of caffeine in rehydation solution is old and well known. Above references in combination makes clear that the formulation containing diemthyglycine, one or more digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose and inositol), minerals, caffeine, glycerol and vitamins are old and well known.

In addition, it would have been apparent to those skilled in the art to optimize amounts of known active and inactive ingredients in a composition. Determination of the appropriate dosage amounts for treatment involving each of the above mentioned formulations is routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed herein.

Conclusion

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614